

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION**

GILDA HAGAN-BROWN,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana
corporation,

Defendant.

Case No. 1:14-cv-01614-AJT-JFA

Hon. Anthony J. Trenga
Hon. John F. Anderson

JANINE ALI,

Plaintiff,

v.

ELI LILLY AND COMPANY, an Indiana
corporation,

Defendant.

Case No. 1:14-cv-01615-AJT-JFA

Hon. Anthony J. Trenga
Hon. John F. Anderson

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTIONS *IN LIMINE*

TABLE OF CONTENTS

TABLE OF CONTENTS..... i

MEMORANDUM IN SUPPORT OF PLAINTIFFS’ MOTIONS *IN LIMINE* 1

I. Plaintiffs’ Motion *in Limine* No. 1: Motion to Exclude Argument, Evidence, and Testimony about the Labeling and Medication Guides for Paxil, Zoloft, Celexa, Lexapro, Effexor, and Lyrica..... 1

II. Plaintiffs’ Motion *in Limine* No. 2: Motion to Exclude Testimony about What a “Reasonable Physician” Would Understand about Cymbalta Withdrawal upon Reading the U.S. Cymbalta Label..... 4

III. Plaintiffs’ Motion *in Limine* No. 3: Motion to Exclude Argument, Evidence, or Testimony about How People other than Plaintiffs Benefited from Cymbalta 5

IV. Plaintiffs’ Motion *in Limine* No. 4: Motion to Exclude Argument, Evidence, or Testimony about Lilly’s or Any Lilly Witnesses’ Charitable Activities, Civic Activities, or Other Such Benevolent Conduct..... 5

V. Plaintiffs’ Motion *in Limine* No. 5: Motion to Exclude Argument, Evidence, or Testimony Concerning Attorney Advertising or Any Claim that this Lawsuit Is Lawyer-Driven 6

VI. Plaintiffs’ Motion *in Limine* No. 6: Motion to Exclude Argument, Evidence, or Testimony that the FDA Has Never Sanctioned Lilly for Its Discontinuation Warning..... 6

VII. Plaintiffs’ Motion *in Limine* No. 7: Motion to Exclude Argument, Evidence, or Testimony that Anyone Other than Lilly Bears Ultimate Responsibility for the Cymbalta Labeling..... 7

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTIONS *IN LIMINE*

I. Plaintiffs' Motion *in Limine* No. 1: Motion to Exclude Argument, Evidence, and Testimony about the Labeling and Medication Guides for Paxil, Zoloft, Celexa, Lexapro, Effexor, and Lyrica

Defendant Eli Lilly and Company ("Lilly") will likely seek to introduce into argument, evidence, and testimony about the labeling of non-Lilly products, such as Paxil, Zoloft, Celexa, Lexapro, Effexor, and Lyrica. Specifically, Lilly will seek to introduce the drug labels, medication guides, and regulatory correspondence for other antidepressants and fibromyalgia medications. Plaintiffs anticipate that Lilly's counsel and expert witnesses will argue to the jury that Cymbalta's label is similar to other drugs regarding warnings about discontinuation, leveraging any similarities to suggest that the Cymbalta's label must be adequate—the "everybody else was doing it" defense. Such argument, evidence, and testimony are inadmissible because (1) it is based on inadmissible hearsay, (2) it is irrelevant, (3) and will lead to undue jury confusion and prejudice.

Hearsay. Lilly will argue that because other antidepressants or fibromyalgia medication labels contain wording about withdrawal that is similar (although slightly different) to Cymbalta, the Cymbalta label is adequate. Such an argument, however, presupposes that the information in non-Lilly labels or medication guides is admissible. It is not. Any non-Lilly label or medication guide, i.e., labels for Paxil, Zoloft, Celexa, Lexapro, Effexor, and Lyrica, are out-of-court statements by competing pharmaceutical companies, i.e., "written assertion[s]," being offered for "the truth of the matter asserted" in the documents. Fed. R. Evid. 801(a). Thus, such labels and medication guides are inadmissible hearsay. Fed. R. Evid. 802. And, since the labels were drafted by non-parties, establishing foundation for potential hearsay exceptions is untenable.

Lilly may argue that this information is admissible under Fed. R. Evid. 703, as reliance

material for Lilly's expert Karen Becker, Ph.D. However, in her report, Dr. Becker merely notes that other labels also contain class labeling about withdrawal. Exh. A at 19-21. She does not explain in any detail how the labels of non-Lilly products are similar or different in the non-class labeling portions or, more importantly, why any such similarities or differences make the Cymbalta label more or less adequate. Any testimony she may want give beyond merely stating that other labels contain class labeling would go beyond the opinions she expressed in her expert reports and are, thus, inadmissible. Moreover, otherwise inadmissible evidence can only be submitted to the jury under Rule 703 when the inadmissible evidence's "probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect." And here, as described below, without the underlying withdrawal data for these drugs or some actual foundation about whether those other drugs' labels are, themselves, adequate, the label language for other drugs lacks *any* probative value, and only serves to give any similar language in the Cymbalta label an unfounded *imprimatur* of adequacy. Lilly cannot show that the otherwise inadmissible evidence's probative value outweighs, let alone *substantially* outweighs, the inherent prejudice of presenting non-Lilly non-Cymbalta drug labels and medication guides to the jury.

Relevance. One issue at the core of this lawsuit is whether the Cymbalta label adequately discloses the risks of withdrawal relative to the data and information that Lilly possessed, such that Lilly discharged its duty to warn under Virginia law. The jury will need to consider the data and information in Lilly's possession regarding Cymbalta withdrawal and determine whether the Cymbalta label, as written, adequately discloses Cymbalta's withdrawal risk. Looking at the language of other drug labels or medication guides has no bearing on that inquiry and does not make it more or less likely that the Cymbalta label was adequate. Other drug labels may,

themselves, be adequate or inadequate, depending on the underlying data. Thus, allowing other labels into evidence will generate mini-adequacy trials for each of those labels—after all, any probative value of similarities between the Cymbalta label and other drugs would require a showing that those other labels are also adequate. The Court should not go down this rabbit hole.

Prejudice and Confusion. Allowing Lilly to present non-Cymbalta labeling and medication guides to the jury will lead to considerable juror confusion and would be unduly prejudicial to Plaintiffs. This lawsuit is about the adequacy of the Cymbalta label. Should Lilly introduce other non-Cymbalta labeling, it will suggest to the jury that Cymbalta was simply doing what everyone else was doing—even though there are differences between the various labels.¹ To rebut this argument, Plaintiffs will need to spend considerable time discussing the data associated with those other drugs and parse the language of each label in comparison to the Cymbalta label. Such an exercise offers little probative value to the jury, wastes time, and poses a significant risk of leading the jury to make an improper inference that just because another drug has similar language, the Cymbalta label must be adequate. The jury is likely to get confused with so many different labels. Accordingly, the risks of jury confusion, prejudice, and waste of time substantially outweigh whatever probative value this evidence may provide. *See* Fed. R. Evid. 403.

Accordingly, Lilly should be excluded from offering argument, evidence, and testimony about the labeling and medication guides for Paxil, Zoloft, Celexa, Lexapro, Effexor, and Lyrica.

¹ For example, depending on the year, the Effexor label does not contain any 1% language, but gives detailed information about the relationship of dose and duration of treatment to withdrawal. In some years, the Paxil label contains a 2% threshold, similar to Cymbalta, but then goes on to specifically list the incident rates of each symptom. In other years, the Paxil label does not list specific incident rates for withdrawal symptoms, but gives a detailed dose-specific recommendation for tapering in stark contrast to the Cymbalta label. There are dozens of iterations of these non-Cymbalta labels, and distinguishing how they are materially different than the Cymbalta label is not valid use of the jury's time.

II. Plaintiffs' Motion *in Limine* No. 2: Motion to Exclude Testimony about What a "Reasonable Physician" Would Understand about Cymbalta Withdrawal upon Reading the U.S. Cymbalta Label

Plaintiffs agreed to limit the testimony of Joseph Glenmullen, M.D., and Louis Morris, Ph.D., concerning any opinion about what a "reasonable" physician would think upon reading the Cymbalta label. Plaintiffs request that such a limitation also be placed on Lilly's experts Michael Clark, M.D., and Karen Becker, Ph.D.—what is good for the goose is good for the gander. Dr. Clark's report states:

In my experience reviewing medication labels as a practicing psychiatrist, I believe that a reasonable physician would *not* read the "1%" in the warning to mean that discontinuation symptoms occur at a rate of only 1% of Cymbalta-treated patients. A reasonable physician would understand that the 1% figure reflects the reporting threshold, listing each specific symptom that occurred above that threshold, and that it does not reflect the specific frequency of the symptom.

Exh. B at 18. Dr. Becker's Report states:

It [Cymbalta label] does not mean that only 1% of patients, and no higher, will experience a DEAE, nor in my opinion would a reasonable medical professional reviewing labeling be misled by such common language in drug labels.

Exh. A at 15. For the very reasons that Lilly opposes having Dr. Glenmullen and Dr. Morris not speculate about what a reasonable physician would think, Dr. Clark and Dr. Becker should not be allowed either. To be sure, they are permitted to testify that they, in their individual and expert capacity, read the label a specific way—just as Dr. Glenmullen and Dr. Morris will. *See, e.g., In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, No. 3:09-CV-10012-DRH, 2011 WL 6732245, at *13 (S.D. Ill. Dec. 16, 2011) (allowing physician to testify about he specifically understands the label). But, going beyond such an opinion to speculate about what "a reasonable physician" would think is not appropriate. *See, e.g., In re Rezulin Products Liab. Litig.*, 309 F. Supp. 2d 531, 556 (S.D.N.Y. 2004) (excluding opinions about what other physicians think). The jury will consider the various opinions of the experts and make a

determination, for themselves, whether the Cymbalta label is sufficiently accurate to disclose the actual risks of Cymbalta withdrawal.

III. Plaintiffs' Motion *in Limine* No. 3: Motion to Exclude Argument, Evidence, or Testimony about How People other than Plaintiffs Benefited from Cymbalta

Lilly will likely offer argument, evidence, or testimony that Cymbalta has “helped millions” or attempt to relay specific stories where Cymbalta has been effective for some person other than the Plaintiffs. Such evidence is inadmissible because it is irrelevant and unduly prejudicial. The fact that Cymbalta has helped another person or even “millions” of people does not make any element of Plaintiffs’ causes of action more or less likely. *See* Fed. R. Evid. 402. This case is about the Plaintiffs’ experiences with Cymbalta, not some random person unconnected to this litigation. Moreover, statements about Cymbalta helping “millions” or even a specific person is impossible, in the context of trial, to verify and is inherently speculative. More to the point, however, it would improperly invoke the sympathies of the jury, untethered to evidence or testimony. This case is not about whether Cymbalta has helped millions or some random person, it is about whether Cymbalta hurt the Plaintiffs. Lilly should be prevented from offering any argument, evidence, or testimony about whether Cymbalta helps millions or elicit personal stories about a person’s, other than Plaintiffs, success using Cymbalta.

IV. Plaintiffs' Motion *in Limine* No. 4: Motion to Exclude Argument, Evidence, or Testimony about Lilly’s or Any Lilly Witnesses’ Charitable Activities, Civic Activities, or Other Such Benevolent Conduct

Lilly will likely offer argument, evidence, or testimony that the company engages in significant charitable activities or that specific company witnesses are involved in some form of benevolent conduct in an effort to obtain goodwill from the jury. Such evidence is inadmissible because it is irrelevant and unduly prejudicial. Any parties’ charitable activities have *nothing* to do with this case. It would only serve to play to the jury’s sympathies and engender goodwill

untethered to any evidence. Whether Lilly or its company witnesses engage in charitable conduct does not influence any element of any cause of action.

V. Plaintiffs’ Motion *in Limine* No. 5: Motion to Exclude Argument, Evidence, or Testimony Concerning Attorney Advertising or Any Claim that this Lawsuit Is Lawyer-Driven

Lilly will likely attempt offer argument, evidence, or testimony that these cases were generated or “driven” by lawyers or lawyer advertising. Such evidence is inadmissible because it is irrelevant and unduly prejudicial. Argument or testimony that these lawsuits were driven by lawyer advertising—a fact that is unfounded—would not make any fact at issue in this case more or less likely. *See* Fed. R. Evid. 401. But even assuming any probative value, these kinds of arguments clearly violate Fed. R. Evid. 403 as \any probative value of such evidence is substantially outweighed by a risk of unfair prejudice to the Plaintiffs. Indeed, the only purpose of such argument would be to prejudice the jury against Plaintiffs by playing to preconceptions about tort reform or other completely irrelevant issues. Lilly should be excluded from making any argument or offering any testimony about whether this case (or others) are lawyer driven.

VI. Plaintiffs’ Motion *in Limine* No. 6: Motion to Exclude Argument, Evidence, or Testimony that the FDA Has Never Sanctioned Lilly for Its Discontinuation Warning

Lilly will likely offer argument, evidence, or testimony that the FDA has never taken an adverse action against Lilly related to its Cymbalta withdrawal warning. Such evidence is inadmissible because it is irrelevant and unduly prejudicial. “The fact that Defendant has not been cited by the FDA for its labeling, marketing, or subject drugs is not proof of compliance with FDA regulations.” *Georges v. Novartis Pharm. Corp.*, No. CV 06-05207 SJO VBKX, 2013 WL 5217198, at *6 (C.D. Cal. Apr. 4, 2013). Indeed, the failure to act by the FDA has no bearing on whether, under Virginia law, the Cymbalta labeling is adequate. Lilly is welcome to affirmatively argue that it complied with FDA regulations—with the understanding that Dr.

Morris will testify that Lilly did not. But, citing the lack of regulatory action as evidence of compliance misapprehends the regulatory framework and is a direct assault on the Supreme Court's clear holding that "the manufacturer bears responsibility for the content of its label at *all times*. It is charged both with crafting an adequate label and with *ensuring that its warnings remain adequate as long as the drug is on the market*." *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009) (emphasis added). Argument, evidence, or testimony that the FDA has never taken an adverse action against Lilly related to its Cymbalta withdrawal warning is misleading and inappropriate, and is "likely to cause delay and to mislead and confuse the jury." *Georges*, 2013 WL 5217198, at *6.

VII. Plaintiffs' Motion *in Limine* No. 7: Motion to Exclude Argument, Evidence, or Testimony that Anyone Other than Lilly Bears Ultimate Responsibility for the Cymbalta Labeling

It is black letter law that "the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Levine*, 555 U.S. at 570-71. Lilly should be prevented from presenting evidence or argument to jury contradicting this simple and bold assignment of label responsibility. *Wolfe v. McNeil-PPC, Inc.*, No. CIV.A. 07-348, 2012 WL 38694, at *9 (E.D. Pa. Jan. 9, 2012). Lilly is welcome to offer evidence that the FDA approved the label, but cannot argue to the jury or present corresponding testimony that the FDA is ultimately responsible for the content of the label. This is particularly important since lay jurors will not understand the regulatory framework governing medications and it is easy to believe (incorrectly) that the FDA is solely responsible for drug labeling.

Dated: August 3, 2015

Respectfully submitted,
MILLER LEGAL, LLC

/s/ Peter A. Miller
Peter A. Miller, Esq. (Va. Bar 47822)
pmiller@millerlegalllc.com
175 S. Pantops Drive, Ste. 301
Charlottesville, VA 22911
Tele (434) 529-6909
Fax (888) 830-1488

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
R. Brent Wisner, Esq. (*pro hac vice*)
rbwisner@baumhedlundlaw.com
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Tel: (310) 207-3233
Fax: (310) 820-7444

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, Brent Wisner, hereby certify that on the 3rd day of August, 2015, a true copy of the foregoing MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTIONS *IN LIMINE* was filed electronically with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

Jeffrey Todd Bozman
Michael X. Imbroscio (*pro hac vice*)
Phyllis A. Jones (*pro hac vice*)
Brett C. Reynolds (*pro hac vice*)
COVINGTON & BURLING LLP
One City Center
850 Tenth Street, NW
Washington, DC 20001
Tele (202) 662-5335
Fax (202) 778-5535

/s/ Peter A. Miller

Peter A. Miller
MILLER LEGAL LLC
175 S. Pantops Drive, Ste. 301
Charlottesville, VA 22911
Tele (434) 529-6909
Fax (888) 830-1488
pmiller@millerlegalllc.com